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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM22/0821

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EXAMINER

DAZLS

ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

08/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/619,493

Applicant(s)
Norman Mashed

Examiner
Sabiha Qazi

Art Unit
1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 19, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s)1, 2, 9, 10, 11, 14, and 18 drawn to method of treating premenstrual dysphoric order (PMDD) comprising drospirenone, classified in class 514, subclass 178+.

Group II, claim(s)1, 2, 9, 10, 11, 14, and 18 drawn to method of treating premenstrual dysphoric order (PMDD) comprising cyprosterone acetate, classified in class 514, subclass 178+.

Group III, claim(s)1, 2, 9, 10, 11, 14, and 18 drawn to method of treating premenstrual dysphoric order (PMDD) comprising dienogest, classified in class 514, subclass 178+.

Group IV, claim(s)1, 3, 4-8, 12, 13, 15-17, 19-23, drawn to method of treating premenstrual dysphoric order (PMDD) comprising dienogest (gestagen) and ethinylestradiol (estrogen), classified in class 514, subclass 178+.

Group V, claim(s)1, 3, 4-8, 12, 13, 15-17, 19-23, drawn to method of treating premenstrual dysphoric order (PMDD) comprising drospirenone (gestagen) and ethinylestradiol (estrogen), classified in class 514, subclass 178+.

Group VI, claim(s)1, 3, 4-8, 12, 13, 15-17, 19-23, drawn to method of treating premenstrual dysphoric order (PMDD) comprising cyprosterone acetate (gestagen) and ethinylestradiol (estrogen), classified in class 514, subclass 178+.

If applicants want to elect the invention other than those cited above, they may elect a species and Examiner will build a group as cited above for examination.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: .

1. The claims are deemed to correspond to the species listed above in the following manner:

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: estrogens such as ethinylestradiol, estratriene triol, dialkyl derivatives of

estradiol, dienogest, drospirenone, cyrosterone acetate, estrogen, estradiol valerate, estradiol ester, gestagen and others. Each will required a separate search. A prior art used for one invention cannot be used for the others. These are not art recognized equivalents. It will be a burden on the Examiner to examine all the inventions as instantly claimed.

A telephone call was made to Attorney Anthony Zelano on 8/10/01, to request an oral election to the above restriction requirement, but did not result in an election being made.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Accordingly, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Claims are drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, which is

broad and includes dozens of compounds as cited above which does not belong to the same technical feature. It would be a burden on the examiner to search the whole invention as claimed.

It is suggested that in order to advance prosecution, the non elected subject matter be canceled when responding to this office action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

S. Qazi

Sabiha N. Qazi Ph.D.

Primary Examiner

Art Unit 1616

8/17/01